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Italo Colombo

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EXAMINER

PALENIK, JEFFREY T

ART UNIT

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/540,139	<b>Applicant(s)</b> COLOMBO ET AL.	
	<b>Examiner</b> Jeffrey T. Palenik	<b>Art Unit</b> 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Applicants' amendments and remarks filed 18 December 2008 are acknowledged and entered on the record. The Examiner acknowledges the following:

Claims 11-20 have been cancelled. Claim 21 was added.

Claims 1-10 have been amended. Regarding claim 1, the organic carrier limitation has been amended to reflect a "particulate" organic carrier. The compounds defining water-soluble complexing agents have been removed and set forth in new claim 21. Thus, support for the new claim is clearly presented in the originally submitted claims. This amendment is interpreted by the Examiner as broadening the scope of claim 1.

Though not expressly stated in the response, support Applicants' remaining amendments was found within the disclosure.

Thus, claims 1-10 and 21 now represent all claims currently under consideration.

### **INFORMATION DISCLOSURE STATEMENT**

No new Information Disclosure Statements (IDS) have been submitted for consideration.

### **WITHDRAWN OBJECTIONS/REJECTIONS**

#### **Objection to the Specification**

Applicant's amendment to the Abstract of the Invention, submitted 6 January 2009, has been considered fully and is persuasive. Thus, said objection has been **withdrawn**.

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Rejection under 35 USC 112

Applicants' amendments to claim 1 removing the terms "massively" and "it" and clarifying the language regarding the percent by weight of the amorphous form of the drug, render moot the rejection, under 35 USC 112, second paragraph. Thus, said rejection has been **withdrawn**.

Applicants' remarks to claims 7 regarding the term "loaded with", as well as claim 10 regarding the term "sparingly", particularly with regard to the common showing of the respective uses in the art, are sufficient to render moot the rejection, under 35 USC 112, second paragraph. Thus, said rejections have been **withdrawn**.

Rejections under 35 USC 102(b) and 35 USC 103(a)

Applicants have perfected their foreign priority to Italian Application No. MI2002A002748 and said document has been verified as lending support to the instant disclosure. Since Applicants' priority has been perfected, the Bergese reference (see *Materials Science and Engineering* NPL), published in 2003, is disqualified as prior art. Thus the rejection of claims 1-3 and 6-10, under 35 USC 102(b), as being anticipated by Bergese as well as the rejection of claims 1-10, under 35 USC 103(a), as being unpatentable over the combined teachings of Bergese et al. and Miyamoto et al. are both rendered moot. Thus, said rejections now stand **withdrawn**.

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### **MAINTAINED REJECTIONS**

The following rejection is maintained from the previous Office Correspondence dated 18 August 2008:

### **CLAIM REJECTIONS - 35 USC § 112**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Dependent claim 6 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter that is not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Claim 6 is drawn to a method limitation wherein the step is carried out in a container constituted of “dielectric material”. While the Examiner acknowledges that the term “dielectric material” is mentioned in the instant specification, the term is not defined by the instant specification in a clear and concise manner. Applicants provide a single “preferred” example for said material in the form of polytetrafluoroethylene loaded with carbon (see pp. 3 and 6 in Applicants’ spec.) and it is unclear what other materials Applicants’ define as part of the invention. As such, the disclosure of the instant specification is not sufficient to support the generic concept of “dielectric material” and requires further clarification. As construed in the prior art, the Examiner is interpreting the term “dielectric material” as a material which conducts electricity poorly, but supports an electrostatic field (see [www.whatis.techtarget.com](http://www.whatis.techtarget.com)).

### **RESPONSE TO ARGUMENTS**

Applicants' arguments with regard to the rejection of claim 6 under 35 USC 112, first paragraph, have been fully considered and are considered to be persuasive in part.

Applicants allege that the written description requirement has been met since the instant disclosure discusses "dielectric material" in terms of a material that increases in temperature in proportion to the power applied, when exposed to microwaves.

In response, the Examiner concedes the rejection in terms of the broader definition of the term "dielectric material" (i.e. the property of the material). However, the rejection is maintained because Applicants' disclosure discusses only one compound which may embody said material, namely PTFE infused with graphite. Since Applicants' disclosure mentions only the preferred species of the broader genus of dielectric materials, the Examiner respectfully maintains that a lack of written description for the genus remains. Otherwise, stated it is not clear to the ordinarily skilled artisan what other materials may embody a dielectric material within the scope of the instant invention.

For these reasons, Applicants' arguments are found unpersuasive. Said rejection is therefore **maintained**.

### **NEW OBJECTIONS/REJECTIONS**

In light of Applicants' remarks and amendments, as discussed above, the following rejections have been newly added:

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**CLAIM REJECTIONS - 35 USC § 112**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a limited class of water-soluble complexing agents, namely the preferred cyclodextrins and maltodextrins (see paragraph bridging pp. 4-5 of the disclosure), does not reasonably provide enablement for the generic class of “water-soluble complexing agents”. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The limitation “water-soluble complexing agents” is extremely broad and encompasses an extremely large class of agents. Given its broadest reasonable interpretation, any water-soluble complexing agent, admixed with a drug, would read on Applicants' instantly claimed mixture. To this end, given that the instant invention is drawn to a method for mixing a drug with a water-soluble complexing agent and then irradiating said mixture to achieve a an active composite compound, the Examiner respectfully submits that one of ordinary skill in the art would be faced with an undue experimental burden in attempting to practice the invention commensurate in scope with the claims. That is, the instant invention is concerned with only a limited subclass of water-soluble complexing agents, the aforementioned cyclodextrins and maltodextrins of the instant specification, and an ordinary practitioner would need to undergo undue experimentation in order to develop an effective method for producing a drug/carrier solid dispersion using the instantly claimed method without guidance from the prior art. As such, the

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disclosure of the instant specification is not sufficient to support the generic concept of “water-soluble complexing agents”.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The amended recitation of “a particulate organic carrier” render the claims indefinite particularly since it is unclear what Applicants definition of a particulate is with respect to the instant invention. Broadly interpreted, a carrier in particulate form may comprise a sprayed liquid carrier or a solid granular particulate form.

The amended limitation which recites that the formed composite contains “the drug dispersed within the particulate organic carrier deposited both on the surfaces and inside the organic carrier particles” renders the claim indefinite because the language used is unclear. It is particularly unclear if Applicants intend to have the drug dispersed only within the carrier or completely throughout the carrier. The recited term “surfaces” also renders the claim indefinite since it is unclear how the composite comprises multiple surfaces.



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### CLAIM REJECTIONS - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of Aoki (EP 1 308 156 A1) and Miyamoto et al. (USPN 6,462,093).

The instantly amended claim 1 is drawn to a process for preparing a composite containing a drug in an organic carrier. Said method comprises first mixing a drug with an organic carrier,

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wherein said carrier is selected from a water-soluble complexing agent and water-insoluble cross-linked polymer. Second, the mixture is subjected to microwave irradiation such that the temperature of the mixture is increased above the melting point of the drug and maintained for at least five minutes. That the method forms a composite containing the drug dispersed throughout the carrier is present in the amorphous form equal to or greater than 50% by weight of the total amount of the drug, as recited in claim 1 is considered by the Examiner as being the expected result of performing the instantly claimed method. Thus, with regard said limitation, until some material difference in the properties of the method are demonstrated, said product limitation is considered by the Examiner to be directed toward the method, which is instantly claimed.

Claims 2 and 3 recite limitations to the method such that the drug/carrier mixture is further mixed with a solvent such as water, to form a wet mixture prior to heating. Claim 8 recites that the microwave heating step of claim 1 is carried out within the power range of 100-5,000 Watts and for a period of time up to 120 minutes. Claim 10 recites that the drug which is used in the method is sparingly soluble (e.g. difficult to dissolve) in water.

Aoki teaches the preparation of a solid dispersion composition comprising a slightly water-soluble medicament blended with a water-soluble polymer, exposed to microwaves ¶[0008]. The medicament/polymer mixture is further expressly taught as being combined with water in an amount which preferably ranges from 0.8-30% by weight ¶[0011]. Slightly-soluble medicaments such as nifedipine are taught in ¶[0008] and the Examples. Embodiments of the water-soluble polymer are taught in ¶[0019] and include polymers such as hydroxypropyl methylcellulose-acetate succinate (HPMC-AS). The organic water-soluble polymer is further taught as being in particle form. Paragraph [0014] teaches that the components may be

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combined to form a wet-granulated composition. Lastly, microwave exposure to melt the slightly soluble medicament and/or the water-soluble polymer to form the solid dispersion is taught as occurring for a maximum time of four minutes (Fig. 1 and 2, ¶[0011]). A microwave power level of 630 watts is expressly taught as being used for nifedipine mixtures (see Examples).

Aoki does not expressly teach that the temperature achieved during the microwave heating step, is above the melting point of the slightly soluble medicament, nor is it taught that microwaving occurs for longer than four minutes.

Miyamoto et al. teaches a process for producing a solid dispersion of a sparingly water-soluble substance which comprises subjecting said sparingly water-soluble substance, an amorphous state-inducing agent and an amorphous state-stabilizing agent to high-frequency heating (Abstract). The mixture of the aforementioned three ingredients allows for the sparingly water-soluble substance to be made amorphous and dispersed within its carrier at a lower temperature. Combining the sparingly water-soluble substance and the amorphous state-inducing agent is taught as a means for achieving a depressed melting point temperature (i.e. one which is below that of either the substance or the agent), thereby allowing the mixture to be preferably heated at a temperature which is not more than the melting point of the sparingly water-soluble medical substance (col. 4, lines 30-53 and col. 6, lines 27-43). Examples 1 and 4 expressly teach the solid state dispersion of nifedipine within an organic carrier. Example 1 teaches the mixture of five grams (e.g. 5 mL) of water with 10 g of nifedipine, and 20 g of hydroxypropyl methylcellulose-acetate succinate (HPMC-AS). Such a mixture was

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demonstrated by the teachings of Aoki. However, Miyamoto further adds 10 g of the amorphous state-inducing agent, succinic acid, to the formulation, thereby depressing the melting point temperature of the mixture. Example 4, which uses the wet granulation formulation of Example 1, teaches heating the mixture to 160°C for 20 minutes using a microwave set to 700 watts.

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to have devised the instantly claimed method and achieved the resulting composition by adding an agent such as succinic acid (e.g. an amorphous state-inducing agent) to the formulation of Aoki and increasing the period of microwave exposure time. The ordinarily skilled artisan would have been highly motivated to do adjust the method (i.e. extend the exposure time), particularly in view of the fact that Aoki and Miyamoto both expressly teach the formation of wet granulated compositions comprising nifedipine and HPMC-AS as well as irradiating said compositions via microwave radiation. The teachings of Miyamoto suggest that further combining the mixture with an amorphous state-inducing agent such as succinic acid not only lowers the melting point temperature of the slightly soluble medicament, but also enables the mixture to be exposed to higher wattages of microwave radiation for longer periods of time.

Based on the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, alone or in combination, especially in the absence of evidence to the contrary.

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Claims 4, 5, 9 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miyamoto et al. as set forth above with respect to claims 1-3.

The method of claims 1-3 is further limited by claim 4 such that the water is recited as being added to the drug/carrier mixture ranging from 0.1-5.0 mL water/gram of drug/carrier mix. The limitation recited by claim 5 states that application of the oscillating EM field occurs at a pressure of 1-20 bar. Claim 9 further limits the cross-linked polymer recited in claim 1 whereas claim 21 further limits the water-soluble complexing agents.

The teachings of Miyamoto are discussed above. Examples 1 and 4, in particular teach the use of HPMC-AS as the amorphous state-stabilizing agent. Miyamoto also expressly teaches cross-linked polyvinylpyrrolidone (e.g. crospovidone) as well as  $\alpha$ -,  $\beta$ -, and  $\gamma$ -cyclodextrins as functionally equivalent amorphous state-stabilizing agents (col. 5, lines 18-26, 45 and 46), thereby teaching the limitations of claims 9 and 21. The cyclodextrins are preferably taught as being functionally equivalent to HPMC-AS (col. 5, line 66 to col. 6, line 3). The limitation of claim 4 is expressly taught by Examples 1 and 4, whereby the amount of water (e.g. 5 grams or 5 mL) admixed with the drug (e.g. 10 grams nifedipine), the amorphous state-stabilizing agent (e.g. 20 grams HPMC-AS) and amorphous state-inducing agent (e.g. 10 grams succinic acid) results in a wet granulated mixture of about 0.125 mL water per gram of dry ingredient. Regarding the limitation of claim 5, it is broadly and reasonably interpreted by the Examiner as the method being performed at standard atmospheric pressure. Standard atmospheric pressure is well known in the art as being: 1 atmospheres, which is equivalent to about 1.01325 bar. Though the teachings of Miyamoto are silent as to the pressure at which the method is performed, save

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for the drying step of Example 2, it is concluded, absent evidence to the contrary that the method is performed in an environment incorporating standard atmospheric pressure (i.e. a lab).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to have substituted either crospovidone or a cyclodextrin compound into the method of Miyamoto for HPMC-AS, which is expressly taught. The ordinarily skilled artisan would have been highly motivated to make the aforementioned substitution, especially for  $\alpha$ -,  $\beta$ -, or  $\gamma$ -cyclodextrin, particularly since the cyclodextrin compounds are taught as preferable and equivalent alternatives for HPMC-AS (col. 5, line 66 to col. 6, line 3).

Based on the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, alone or in combination, especially in the absence of evidence to the contrary.

Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of Miyamoto et al. and Aoki et al. as set forth above with respect to claim 1 in combination with Lautenschläger (USPN 5,447,077).

The instant claim 6 recites that the method of claim 1 is performed using a container comprised of a dielectric material having a coupling capacity with microwaves. Claim 7 recites that said material is polytetrafluoroethylene loaded with graphite (e.g. Weflon<sup>®</sup>).

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The teachings to both Miyamoto and Aoki are discussed above. Though it is inherently concluded that the methods to both are performed using a microwave-conductive container, neither reference expressly discusses from what material said container is constructed.

Lautenschläger teaches a device for the evaporation treatment of preferably liquid substances in a container having a preferably microwave-operated heating appliance (Abstract). Figure 23 shows a vertical partial cross-section of the heating area as well as the holder for one or more containers. The container itself is identified as item (6). Lautenschläger teaches that said container(s) are preferably constructed from a microwave-permeable plastic material, preferably polytetrafluoroethylene (PTFE) and that such plastics preferably contain microwave-absorbing particles such as graphite (e.g. Weflon) (col. 8, lines 25-41 and col. 20, lines 8-16).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to have used a container constructed of Weflon<sup>®</sup> with either of the methods of Miyamoto or Aoki particularly since Lautenschläger expressly teaches that the material is constructed from both a microwave-permeable material as well as a material which impedes microwaves, which expressly suggests that the manufacture of the material maybe advantageously adjusted to manage the heat of the microwaved mixture (col. 20, lines 4-7).

Based on the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at

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the time the invention was made, as evidenced by the references, alone or in combination, especially in the absence of evidence to the contrary.

All claims under consideration remain rejected; no claims are allowed.

### CONCLUSION

Due to the new grounds of rejection, this action is deemed **non-final**.

### CORRESPONDENCE

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey T. Palenik whose telephone number is (571) 270-1966.

The examiner can normally be reached on 7:30 am - 5:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey T. Palenik/  
Examiner, Art Unit 1615

/MP WOODWARD/  
Supervisory Patent Examiner, Art Unit 1615